

**Donald F. Fernholz**

**Senior Consultant/Auditor**

**EAS Consulting Group, LLC**

**1940 Duke Street, Suite 200**

**Alexandria, Va. 22314**

**Education:** Northern State University, Aberdeen, South Dakota  
BS Degree - Majors: Biology and Social Science

**Professional  
Experience:**

**Minnesota State Health Department (one year)**  
**St. Paul, Minnesota**

**Position: State Health Sanitarian. Made sanitary inspections  
of food establishments, restaurants, resorts.**

**U. S. Food and Drug Administration**

**Position: Consumer Safety Officer**

**St. Louis, Missouri (one year)**  
**Minneapolis, Minnesota (one year)**  
**Chicago, Illinois (seven years)**  
**Fargo, North Dakota (four years)**

**Position: Supervisory Consumer Safety Officer**

**Akron, Ohio (ten years)**  
**Brunswick, Ohio (ten years)**

**As a Consumer Safety Officer, made inspections of all types  
of food, drug, cosmetic, veterinary drug, device, blood bank,  
plasmapheresis, and medicated feed manufacturers.**

**Food manufacturing facilities were inspected for compliance  
with Good Manufacturing Practices regulations; HACCP  
regulations, if applicable; Low Acid Canned Food  
regulations; and other regulations.**

**Have made numerous inspections of on-farm custom feed mixing operators; medicated feed manufacturers; and have made numerous on-farm inspections to investigate drug tissue residue referrals from the USDA.**

**Have made numerous investigations of incidents involving food poisonings, adverse drug reactions, food and drug contamination incident**

**As a Supervisory Consumer Safety Officer, I hired and trained numerous investigators in all aspects of inspections, investigations, and evidence development.**

**I have received numerous awards during my career with FDA including:**

**Commendable Service Award, "For sustained superior performance in the timely processing of heavy workloads and high priority work with outstanding results"**

**Commendable Service Award, "For exemplary performance in managing the operations of District inspection posts".**

**Letter of Commendation from President Regan for the investigation of a drug tragedy.**

**Seminars/Courses:**

**I presented training in several courses in "Evidence Development" to investigators throughout FDA Region V and received a Letter of Commendation for my efforts.**

**I was a facilitator for a series of "Investment In Excellence" training courses and taught these courses in two FDA regions. I received a Letter of Commendation.**

**I have been a guest lecturer to students for the North Dakota State University, Akron University, and numerous lay groups. Presentations covered FDA law, recall policy, product labeling, evidence development, and several other topics related to FDA.**

**Additional  
Professional  
Activities**

**I have presented numerous training courses to FDA personnel, State and Local Health Department officials and others. The course content included inspection/audit techniques, Good Manufacturing Practices**

regulation evidence development, documentation, HACCP regulations, Low Acid Canned Food regulations, and many other topics.

**Position: Senior Auditor/Consultant**

I have worked as a Senior Auditor/Consultant for two firms and as a self-employed Auditor/Consultant for the past ten years. This included audits and investigations of manufacturers, distributors, warehouses, and growers of a multitude of food products; dietary supplements, misbranded drugs, and food poisoning incidents.

**Professional  
Memberships**

Past member of: Central States Association of Food & Drug Officials  
National Environmental Health Association  
American Institute of Baking

**Training Courses  
Attended**

I have attended numerous training courses to include:

"Quality Audits for Improved Performance"  
"FDA Law & Evidence Development"  
"Advanced Course for Drugs and Parenterals"  
"Low Acid Canned Food Processing"  
"Advanced Course Non-Clinical Bio-Research"  
"Milk Pasteurization Controls and Tests"  
"Current Concepts in Food Protection"  
"Medical Pharmacology Course"  
"Statistical Quality Control"  
"Advanced Course for Drug Inspectors: Blood Banks"  
"Hazard Analysis and Critical Control Points"  
"Good Agricultural Practices" audits

  
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